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09/303,716	04/30/1999	MICHAEL J. POWELL	0039021-0040	8751

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06/20/2002

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 18

Application Number: 09/303,716
Filing Date: April 30, 1999
Appellant(s): POWELL ET AL.

Barry Evans
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/7/02.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

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(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 36, 39, 42, 45 and 48. Claims 26-34, 37, 40, 43, 46 and 49 are withdrawn from consideration as not directed to the elected invention. Applicant states that "[c]laims 1-35, 37-38, 40, 41, 43, 46, 47 and 49 are cancelled", however the examiner cannot find an amendment canceling claims 26-34, 37, 40, 43, 46 and 49.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellants contend that claims 36, 39, 42, 45 and 48 stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 36, 39, 42, 45 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to catalytic antibodies elicited by an antigen of formula (I), and this formula has a very wide range of possibilities; a method for producing a catalytic antibody which catalyzes any chemical reaction "of interest" by using the hapten of formula (I) to elicit a catalytic antibody by exposing cells capable of producing antibodies to the hapten *in vitro* or *in vivo* and then making these antibodies into monoclonal antibodies by a known method; and a method of catalyzing the cleavage or formation of a peptide linkage or ester bond in a molecule by contacting the molecule with the catalytic antibody. The specification teaches how to make the hapten but does not teach that any of the myriad possibilities of formula (I) will make antibodies that have catalytic activity, which molecules are substrates for the cleavage or formation of an ester or peptide bond, nor where it will be cleaved by the antibody. It is maintained that one of ordinary skill in the art reading the instant specification would not reasonably have conveyed to them that appellants had possession of the claimed invention at the time the application was filed.

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(11) Response to Argument

Appellants argue that several specific embodiments of the invention are described in the specification including a method for synthesizing the hapten and a method for producing and isolating monoclonal catalytic antibodies, referencing page 67, line 4 to page 68, line 26 and page 75, line 1 to page 81, line 22. The examiner admits that a method of making the hapten is given and claims drawn to this hapten were allowed in the parent application, and this is disclosed in the cited passage on pages 67-68. However, the teachings on pages 75-81 are general teachings as to possible catalytic cleavages and a possible method to detect these cleavages, but there is nothing in the cited passage that would indicate to one of ordinary skill in the art that applicant had possession of the claimed catalytic antibodies when the application was filed.

Appellants argue that "35 USC § 112, first paragraph specifies that the invention need not be described in such a "...full, clean, concise, and exact terms as to enable any person skilled in the art...to make and use the same..." (emphasis added). To start with, appellants apparently meant to state that "the invention need be described in..." instead of the cited recitation. As outlined in MPEP 2161, the first paragraph of 35 USC § 112 consists of three separate and distinct parts: (1) A written description of the invention, (2) the manner and process of making and using the invention (the enablement requirement) and (3) the best mode contemplated by the inventor of carrying out his invention. The written description requirement is separate and distinct from the enablement requirement. *In re Barker*, 194 USPQ 470 (CCPA 1977); *Vas-Cart, Inc v. Mahurkar*, 19 USPQ2d 1111, 1115 (Fed. Cir 1991). An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a

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disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See *In re Armbruster*, 185 USPQ 152 (CCPA 1975). It is maintained that the instant application is analogous to the second example where a catalytic antibody and a method of making it are disclosed "within broad ranges" but no "specific formulation" is described that would produce the catalytic antibody. *Fiers v. Revel* 25 USPQ 1601 (Fed. Cir, 1993) states that for an application to provide an adequate written description of a nucleic acid, the inventor must be able to envision the detailed structure of the nucleic acid, i.e. have the nucleic acid in hand. A mere method of making the nucleic acid along with its biological activity is simply a wish to know the identity of any material with that activity, not a proper written description of the nucleic acid. A similar argument can be made here in that the instant specification merely states "a wish to know the identity of any material with [the activity of the catalytic antibody and is] not a proper written description" because appellant has not shown one of ordinary skill in the art that he knew at the time the application was filed which embodiments of the very broad range included within the scope of the hapten (formula (I)) would produce a catalytic antibody and which would not. There is not a disclosure of any catalytic antibodies in the specification nor is there an indication that any of the broad embodiments of formula (I) would produce such an antibody.

Appellants argue that: "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can

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identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus". In the instant case it is maintained that the catalytic antibody is sufficiently unpredictable that without some guidance which hapten will produce antibodies that are catalytic and which will only produce antibodies that have no catalytic activity, the broad formula (I) is not adequate written description. Appellants have cited Gao, et al. (U) to show that the catalytic antibody art is predictable, but as discussed in the action of 5/30/03 (Paper No. 12) this reference, along with many others, show that the catalytic antibody art is unpredictable. While the instant reference does show that a trigonal boronic hapten will produce a catalytic antibody, the hapten is not included within the broad range of formula (I). Only one particular hapten (3a) is shown to produce a catalytic antibody and that antibody will act on only one substrate (1a). The catalytic antibody will not cleave the diastereomer (1b) nor the ester substrates (1c or 1d). Applicant argues in the enablement section of the argument that the reference "reduced the half-life of the primary amide in 1a from ca 17.5 years to 3.9 h in the presence of the catalytic Fab", but this only shows that the antibody had catalytic activity, not that the catalytic antibody or haptens that elicit it are predictable.

Appellants further argue that "the specification provides an extensive disclosure of the claimed compounds and a detailed description of the various synthetic methods for preparing such compounds (specification, Example 3...)". This example describes the synthesis of the hapten, not the preparation of catalytic antibodies. As noted *supra*, the haptens have been allowed in the parent application and that is not what is being claimed here.

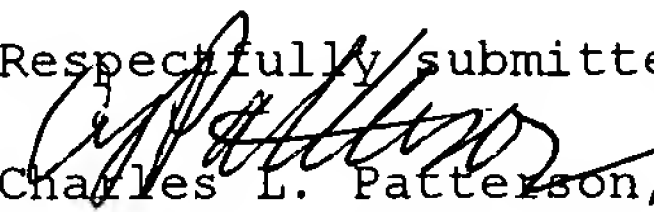
Appellants state that they "believe the Examiner is confusing the 'enablement' and 'written description' requirements under 35 USC § 112, first

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paragraph" and the rest of their arguments are directed the enablement of the instant claims. Since the instant rejection is not an enablement rejection, counter-arguments to these arguments will not be made. The reference by appellants to Nevinsky, et al. are arguments about enablement and, as appellants state, this reference is a review article showing the state of the art in 2000.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652


Patterson
June 19, 2002

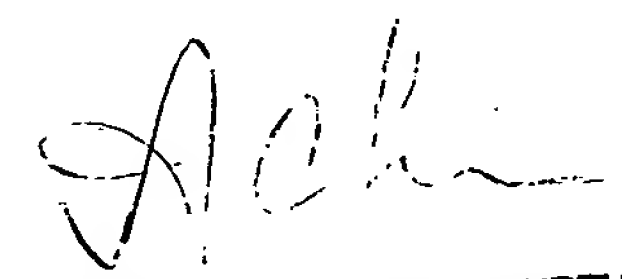
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